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Attorneys for Defendants
C. R. Bard, Inc. and
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability
Litigation,

No. 2:15-MD-02641-DGC

**DEFENDANTS' REPLY IN
SUPPORT OF ITS POST-VERDICT
MOTION FOR JUDGMENT AS A
MATTER OF LAW AND
MEMORANDUM IN SUPPORT**

SHERR-UNA BOOKER, an individual,

(Assigned to the Honorable David G.
Campbell)

Plaintiff,

v.

(Oral Argument Requested)

C. R. BARD, INC., a New Jersey
corporation and BARD PERIPHERAL
VASCULAR, INC., an Arizona
corporation,

Defendants.

The plaintiff's Response to Bard's Post-Verdict Motion for Judgment as a Matter of Law fails to identify sufficient evidence to support the jury's findings on negligent failure to warn and punitive damages. The plaintiff failed to identify sufficient evidence of an alternative warning, which is required by Georgia law; failed to identify sufficient evidence that the G2 Filter fractured at significantly higher rates than other filters; failed to identify sufficient evidence that a warning about an alleged "cascade of complications" would have changed Dr. D'Ayala's decision to use the G2 Filter for Ms. Booker; and failed to identify sufficient evidence that a post-implant warning to Dr. D'Ayala would have avoided Ms. Booker's damages. Moreover, the plaintiff's interpretation of United States Supreme Court precedent about the scope of permissible evidence to support a punitive damages claim is incorrect, and the plaintiff failed to identify sufficient evidence to support the jury's punitive damages award.

The Court should also view Bard's Motion for Judgment as a Matter of Law through the lens of the plaintiff's argument concerning Bard's Motion for a New Trial. In her Response Brief (Doc. 11015) to that Motion, which was filed contemporaneously with her Response to Bard's Rule 50 Motion, Ms. Booker argued that the verdicts regarding strict liability and negligent failure to warn are consistent if and only if the jury found that Bard negligently failed to warn about "evidence shortly before Ms. Booker's implant [between October 2006 and June 2007], or in the years after implant but before the failures were detected [in April 2013]." (Pl. Resp. Br. (Doc. 11015), at 6.) This limited window of time during which a negligent failure to warn could have occurred further supports Bard's position that judgment as a matter of law is appropriate.

I. Georgia Law Requires an Alternative Warning for Failure-to-Warn Claims, and the Plaintiff's Experts Supplied No Such Alternative Warning.

In *Nolley v. Greenlee Textron, Inc.*, No. 1:06-CV-228-MHS, 2007 WL 5369405, at *7 (N.D. Ga. Dec. 6, 2007), Senior District Judge Shoob granted summary judgment on the plaintiff's strict liability and negligent failure-to-warn claims, noting that "plaintiff lacks essential expert evidence as to what alternative warnings would have been heeded. .

1 . . without Dr. Avitan’s opinion, the jurors will not be presented with alternative warnings
 2 and will have no means by which to adjudge whether the existing warnings were
 3 adequate.”¹ In its Order denying Bard’s Motion for Summary Judgment (Doc. 8874), this
 4 Court discussed *Nolley*, and noted that “[t]he jurors in this case, unlike in *Nolley*, will be
 5 presented with proposed warnings and will have a means by which to determine whether
 6 the actual warnings were adequate.” *Id.* at 10. But the jurors were not presented with
 7 proposed warnings at trial, and the plaintiff’s Response briefing does not demonstrate
 8 otherwise. Indeed, the plaintiff’s Response brief illustrates precisely why such an
 9 alternative warning is necessary for the jury to consider: the plaintiff cites testimony of
 10 fact witnesses concerning different filters at different points in time, similar testimony of
 11 experts, internal Bard e-mails and memoranda from varying points in time, G2 testing
 12 results, documents relating to the Recovery Filter, and various different filter failure
 13 modalities from varying points in time. An expert opinion is needed to boil down this
 14 disparate and technical information to an alternative warning that Bard could have
 15 provided to Dr. D’Ayala either before he used the G2 Filter with Ms. Booker or before
 16 Ms. Booker’s filter fracture was discovered. Without an alternative warning, the jury
 17 could not compare anything against the warnings actually provided to Dr. D’Ayala. As
 18 such, the plaintiff has failed to present legally sufficient evidence concerning her
 19 negligent failure-to-warn claim, and judgment as a matter of law is warranted.

20 **II. The Plaintiff Has Insufficient Evidence to Prevail on Her Negligent Failure-to-** 21 **Warn Claim Irrespective of the Alternative Warning Requirement.**

22 From the outset of this case, the plaintiff has predicated her failure-to-warn claim
 23 on the premise that, in her view, the complication rates of Bard filters exceed the
 24

25 ¹ Ms. Booker suggests that *Nolley* should be disregarded because it cites to an Eastern
 26 District of Pennsylvania case that was reversed by the Third Circuit. But *Nolley* cited the
 27 Eastern District of Pennsylvania decision only for the proposition that “in the absence of
 28 expert testimony a jury could not render a just and proper decision as to whether a defect
 in the Ford manual caused [the plaintiff’s] injuries.” The Third Circuit went on to reverse
 the district court’s exclusion of the expert, which has nothing to do with the point of law
 for which Bard cites *Nolley*—Georgia law requires an alternative warning for a failure-to-
 warn claim.

comparable rates of competitive filters. However, expert testimony is required to establish that the G2 Filter had rates that so departed from the norms that failure to disclose them constituted an inadequate warning. *See, e.g., McClendon v. Manitou Ams. Inc.*, No. CV 415-250, 2016 WL 5723671, at *3 (S.D. Ga. Sept. 29, 2016) (noting that expert testimony is required to prove any defect that is complicated and technical in nature); *Rice v. Genentech, Inc.*, No. 1:10-CV-3631-TWT, 2012 WL 205886, at *2 (N.D. Ga. Jan. 24, 2012) (granting summary judgment in a pharmaceutical products liability case on the plaintiff's negligent failure-to-warn claim because the plaintiff offered no expert opinion concluding that the labeling was inadequate) (citing *Miller v. ALZA Corp.*, 759 F. Supp. 2d 929, 938 n.10 (S.D. Ohio 2010) (providing that "the general rule that, in the case of pharmaceutical, 'since the warning is directed to physicians, only they or someone with similar expertise concerning pharmaceuticals would be qualified to determine whether or not the warning was adequate'"). But the expert testimony elicited at trial is insufficient to support a finding of negligent failure to warn given Dr. D'Ayala's testimony.

The plaintiff focused her questioning Dr. D'Ayala about her claims that the G2 Filter has significantly higher rates of fracture than other filters and that Bard allegedly failed to warn him about this significantly higher rate. But at trial, the plaintiff and her experts tacked to a new theory that caudal migration of the G2 Filter leads to a "cascade of complications." Thus, the trial testimony elicited from Dr. D'Ayala does not align with the trial testimony of Ms. Booker's experts. Accordingly, there is insufficient evidence from Ms. Booker's experts at trial that the G2 Filter had a significantly higher rate of fracture than other filters, and there is insufficient evidence that Dr. D'Ayala would not have used the G2 Filter if warned about a cascade of complications.

In her Response brief, the plaintiff cited the following testimony from Dr. D'Ayala:

- D'Ayala Tr., 21:21 to 24:5 (the frequency of device failures is important to Dr. D'Ayala);
- *Id.* at 31:13 to 32:1 (Dr. D'Ayala moved away from Bard's filters because of reports to MAUDE database);

- *Id.* at 32:19 to 33:3 (Dr. D’Ayala remembers Mr. Ferrara as a Bard sales representative);
- *Id.* at 34:7 to 35:2 (Mr. Ferrara did not tell Dr. D’Ayala about increased risks of complication concerning the Recovery Filter);
- *Id.* at 36:11 to 37:20 (Bard does not think that this testimony was played at trial);
- *Id.* at 47:4-7 (Dr. D’Ayala relies, in part, on IFUs);
- *Id.* at 62:25 to 64:2 (Dr. D’Ayala would have used a different filter if he knew of one that had a better safety profile than the Bard filter; and he was asked about a five-fold risk of fracture and embolization, which was related to the Recovery Filter, not the G2 Filter);
- *Id.* at 64:9 to 67:10 (Dr. D’Ayala was asked whether knowing information in 2007 about an article that was published in 2010 about the G2 Filter would have been important);
- *Id.* at 70:9-20 (Dr. D’Ayala testified that he likely would not have used the G2 Filter in 2007 if he knew it carried a 12% or 25% risk of fracture); and
- *Id.* at 126:16 to 127:3 (Dr. D’Ayala testified that if he knew that there was up to a 25% risk of fracture for the G2 filter, he would have taken greater steps to remove the filter after it was placed).

In contrast, Drs. Muehrcke and Hurst testified about totally different issues, as cited in the plaintiff’s Response brief:

- Dr. Muehrcke testified about caudal migration, the caudal migration FMEA analysis, and the alleged “domino effect” (Trial Tr., 697:7 to 698:19; 705:16 to 707:19); caudal migration and the cascade of complications (*id.* at 679:3 to 680:9); and that documents that he reviewed in the litigation were not provided to him by Bard in the course of his medical practice (*id.* at 682:14 to 683:5).
- Dr. Hurst testified that he expected the G2 Filter to behave like a permanent device with regard to migration (Trial Tr., 805:10 to 807:1); that he expects the IFU to be clear and accurate regarding how to use the product and the risks of the product (*id.* at 828:13-20); that the G2 Filter IFU provided a “laundry list” of 32 complications without discussing rates whereas the Simon Nitinol Filter IFU discussed 4 complications (*id.* at 829:2-23); “if Bard had information where its G2 filter – Bard was aware that the G2 filter had increased rates of failure compared to its own filters,” he would want that in the IFU (*id.* at 831:23 to 832:6); Ms. Booker’s G2 Filter did not perform the way that a permanent filter performed (*id.* at 832:7-23); the combination of tilt leading to caudal migration leading to penetration, leading to fracture was not discussed in the IFU (*id.* at 832:13 to 833:24); a reasonable physician would want to know that migration and tilt led to other complications as well as severity of complications (*id.* at 834:19 to 836:8; 847:8-16; 852:10 to 853:12); the EVEREST study was not designed to study the safety and efficacy of the filter over a long-term period (*id.* at 864:24 to 865:5); and that recommendations from Bard about a program to follow up with patients “would have been nice.” (*Id.* at 873:11-22.)

As Bard argued in its Motion, and as the plaintiff illustrates in her Response, the testimony from Dr. D'Ayala about conditions that potentially would have stopped him from using the G2 Filter for Ms. Booker were never addressed by Drs. Muehrcke and Hurst at trial. And the issues addressed by Drs. Muehrcke and Hurst at trial about caudal migration and an alleged "cascade of complications" were never asked of Dr. D'Ayala. As such, depending on which theory the plaintiff pursues, she is missing either expert testimony about rates of risk associated with the G2 Filter, or testimony from Dr. D'Ayala that he would not have used the G2 Filter if he was warned about a cascade of complications.

Moreover, the plaintiff's concession in her Rule 59 Response (Doc. 11015) that the relevant time period for a negligent failure-to-warn claim is between October 2006 (the issue date of the IFU that accompanied Ms. Booker's filter) and June 2007 (when Ms. Booker's filter was placed) requires her to identify what Bard learned during this narrow window of time that triggered a duty to warn, a failure to do so, and that the information would have caused Dr. D'Ayala to forgo using the G2 Filter for Ms. Booker. No such identification of evidence is apparent from the plaintiff's Response or the record.

Although Ms. Booker also claims that Bard should have warned Dr. D'Ayala about information after she received the G2 Filter (sometime between June 2007 and April 2013 when the fractured filter was discovered), she has not identified how any post-placement warning would have avoided her damages without requiring the jury to impermissibly speculate about how Dr. D'Ayala would have contacted her, that she would have returned for a follow up visit, that retrieving the filter would have been appropriate at the time, that she would have consented to retrieval, and that Dr. D'Ayala could have retrieved the filter. *See Lakeside-Scott v. Multnomah Cnty.*, 556 F.3d 797, 802-03 (9th Cir. 2009) ("A reasonable inference cannot be supported by only threadbare conclusory statements instead of significant probative evidence. Consequently, JMOL is appropriate when the jury could have relied only on speculation to reach its verdict.")

For all of these reasons, judgment as a matter of law is warranted.

III. The Proper Scope of Evidence on the Plaintiff's Punitive Damages Claim Was Limited.

Ms. Booker contends that controlling Supreme Court authority is “of limited relevance,” arguing that key cases were “focused on the amount of damages” and “influenced by the financial—rather than the physical—nature of the underlying injuries.” (Pl. Resp. Br. (Doc. 11012) at 11, 13). The central question in *Phillip Morris*, however, was the proper evidentiary *foundation* for an award of punitive damages, not the amount. 549 U.S. 346, 349 (2007). Indeed, the court recognized that “the Constitution imposes certain limits, in respect both to procedures for awarding punitive damages and to amounts forbidden as ‘grossly excessive.’” *Id.* at 353 (emphasis added). More importantly, a defendant’s procedural Due Process rights do not vary depending on the type of harm to the plaintiff. This Court should reject any insinuation that the jury may consider conduct that bears little or no relation to the plaintiff’s harm simply because that harm was physical rather than financial.

As the plaintiff acknowledges, the only circumstance in which *actual*—not hypothetical—harm to non-parties is admissible is if the evidence is the same “conduct that harmed the plaintiff.” *Philip Morris*, 549 U.S. at 355; *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 422–23 (2003) (“A defendant’s dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages.”); *Coulbourn v. Air & Liquid Sys. Corp.*, No. CV-13-08141-PCT-SRB, 2016 WL 5921255, at *1 (D. Ariz. Jan. 6, 2016) (“[T]he conduct must have a nexus to the specific harm suffered by the plaintiff.”). The plaintiff, however, simply concludes that she has shown a nexus between the conduct that harmed her and the evidence presented, without ever explaining that nexus. Nor could she, as she is relying on arguments that the Recovery Filter was defectively designed that carried through to the G2 Filter. But the jury found that Bard had no liability for strict liability or negligent design of the G2 Filter, thus the “direct nexus to the specific harm suffered” by Ms. Booker is missing. (*Cf.* Pl. Resp. Br. (Doc. 11012) at 16 (asserting that Bard’s failure to “make design changes” or

change the filter’s surface finish should support punitive damages on G2 Filter failure-to-warn claim).) Ms. Booker also mentions the “risk of harm from Bard’s filters that were not fully tested,” (*id.* at 14), yet again fails to connect that purported design-related conduct to her harm related to negligent failure to warn about the G2 Filter.² Instead, the plaintiff impermissibly relies on general reprehensibility. *See id.* at 16 (“[I]t is a part of the whole picture regarding what Bard knew.”). Under controlling Supreme Court precedent, however, such evidence cannot support a punitive damages award.

IV. The Plaintiff’s Evidence Did Not Clear the High Bar Under O.C.G.A. § 51-12-5.1(b).

The standard of review on a post-verdict motion for judgment “must be applied in conjunction with the requirement under O.C.G.A. § 51–12–5.1(b) that the evidence must be clear and convincing.” *Kodadek v. Lieberman*, 247 Ga. App. 606, 10, 545 S.E.2d 25, 29 (2001). Thus, the question for this Court is whether there was *clear and convincing* evidence—limited only to evidence having a nexus to the harm found by the jury—to support punitive damages. Because of this high standard, Georgia law is replete with cases affirming directed verdicts on punitive damages claims, even in cases involving medical negligence-type claims. *Roseberry v. Brooks*, 218 Ga. App. 202, 209-10, 461 S.E.2d 262, 268-69 (1995); *Brown v. DeKalb Med. Ctr.*, 225 Ga. App. 4, 6, 482 S.E.2d 511, 514 (1997) (affirming directed verdict on issue of punitive damages where evidence regarding negligence “was far from . . . clear and convincing evidence of an entire want of care”); *see also Ambling Mgmt. Co. v. Purdy*, 283 Ga. App. 21, 32-34, 640 S.E.2d 620, 629-630 (2006) (affirming directed verdict on punitive damages claim where evidence of potential negligent failure to correct problem was not “clear and convincing evidence” to

² One case cited by the plaintiff actually supports Bard’s position as to the evidence relevant to the punitive damages claim. In *Mack Trucks, Inc. v. Conkle*, the punitive damages claim was based only on prior incidents similar to the type of truck driven, and that were caused by circumstances substantially similar to the accident at issue. 263 Ga. 539, 544, 436 S.E.2d 635, 639-40 (1993). The plaintiff does not confine herself to substantially similar conduct here.

1 support punitive damages).³

2 Other courts applying a “clear and convincing” standard distinguish between
3 evidence that may show negligence and the plus-factor required for punitive damages
4 under that high standard. *Martinez v. UPS Ground Freight Inc.*, No. CV-11-0961-PHX-
5 DGC, 2013 WL 173770, at **4-5 (D. Ariz. Jan. 16, 2013) (Campbell, J.) (even if
6 evidence could show “gross negligence or even reckless disregard for the safety of
7 others,” punitive damages law required clear and convincing evidence of “something
8 more,” which was “lacking”); *Amor Ministries v. Century Sur. Co.*, No.
9 313CV01441GPCBGS, 2016 WL 1388077, at *11 (S.D. Cal. Apr. 7, 2016) (granting
10 motion for judgment as a matter of law, and commenting that while defendant’s actions
11 “may have been unreasonable,” they did “not support an inference by ‘clear and
12 convincing’ evidence that [defendant] acted with malice or oppression”).

13 Here, the evidence at trial does not support punitive damages under a “clear and
14 convincing” standard. As in *Heston v. Taser Int’l, Inc.*, 431 F. App’x 586, 589 (9th Cir.
15 2011), where a manufacturer does warn of relevant risks—even if a jury found that the
16 manufacturer should have known of or warned of additional risks—punitive damages are
17 inappropriate. *Richards v. Michelin Tire Corp.*, 21 F.3d 1048, 1059 (11th Cir. 1994)
18 (punitive damages not warranted where defendant complied with motor vehicle warning
19 label safety standards); *Toole v. McClintock*, 999 F.2d 1430, 1436 (11th Cir. 1993)
20 (“[W]hen a manufacturer took steps to warn plaintiff of the potential danger that injured
21 him; those facts bar a finding that defendant was ‘consciously indifferent.’ . . . The . . .
22 warning describes the main harms that Ms. Toole has actually suffered . . .”); *DeLuryea*

23
24 ³ The plaintiff attempts to distinguish the cases cited by Bard, but her distinctions are
25 either incorrect or make no material difference. (Pl. Resp. Br. (Doc. 11012) at 16 n. 53.)
26 For instance, as to *Kodadek*, Ms. Booker emphasizes that the trial court did not grant
27 summary judgment on punitive damages as to a misrepresentation claim (that the doctor
28 had misrepresented the size and risk of a needle fragment). (*Id.*) But she ignores that the
trial court then granted the hospital’s motion for judgment notwithstanding the verdict as
to the punitive damages *for that claim*, and that the court of appeals affirmed this ruling.
545 S.E.2d at 28-29. Thus, to the extent that the plaintiff claims that the conduct was
“precisely the type of actual knowledge and conscious disregard of risk complained of
here,” *Kodadek* in fact supports judgment as a matter of law for Bard. *Id.*

1 *v. Winthrop Labs., a Div. of Sterling Drug, Inc.*, 697 F.2d 222, 230 (8th Cir. 1983)
2 (concluding that, even where evidence showed failure to *adequately* warn of dangers of
3 drug, where drug package inserts did in fact warn of the harm caused, trial court properly
4 held that evidence did not support punitive damages).

5 The plaintiff asserts a “common theme” that “Bard’s filters were not fully tested”
6 and criticizes Bard “launching” a new filter “with only a pilot test” and then changed its
7 design “without even a pilot study.” (Pl. Resp. Br. (Doc. 11012) at 14, 16.) As discussed
8 above, due process precludes use of this design-related evidence to support punitive
9 damages on a negligent failure-to-warn claim. Moreover, by making these arguments, the
10 plaintiff attempts to require testing that the FDA does not. While compliance with
11 industry standards, state of the art, or federal regulations does not conclusively eliminate
12 the potential for liability, “punitive damages . . . are, as a general rule, improper where a
13 defendant has adhered to [applicable] . . . safety regulations.” *Barger v. Garden Way, Inc.*,
14 231 Ga. App. 723, 728, 499 S.E.2d 737, 743 (1998) (internal citations and quotations
15 omitted); *see Mims v. Wright Med. Tech., Inc.*, No. 1:11-CV-213-TWT, 2012 WL
16 1681810, at *5 (N.D. Ga. May 11, 2012) (concluding that plaintiffs would not be able to
17 establish conduct warranting punitive damages by clear and convincing evidence, where
18 medical device manufacturer would not have been permitted to sell device without
19 complying with regulatory standards).

20 In sum, the evidence at trial does not support the “aggravation or outrage”
21 necessary for a punitive damages award, and the Court should enter judgment as a matter
22 of law in Bard’s favor as to this issue.

23 **V. CONCLUSION**

24 For the foregoing reasons, and as discussed in Bard’s Motion, this Court should
25 enter judgment as a matter of law regarding the plaintiff’s negligent failure to warn cause
26 of action and the jury’s award of punitive damages.

1 RESPECTFULLY SUBMITTED this 14th day of May, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of May, 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send email notification of such filing to all attorneys of record.

s/Richard B. North, Jr.
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